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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE

10/671,379

09/25/2003

Thomas K. McDonald

BEAER:65632

1868

24201

7590

LOS ANGELES, CA 90045

07/26/2004

FULWIDER PATTON LEE & UTECHT, LLP **HOWARD HUGHES CENTER** 6060 CENTER DRIVE **TENTH FLOOR**

EXAMINER RAGONESE, ANDREA M

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)	
		10/671,379	MCDONALD ET AL.	
	Office Action Summary	Examiner	Art Unit	
		Andrea M. Ragonese	3743	
Period for	- The MAILING DATE of this communication app r Reply	ears on the cover sheet with th	e correspondence address	
THE N - Exten after S - If the - If NO - Failun Any re	DRTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Sions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, aply received by the Office later than three months after the mailing d patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be within the statutory minimum of thirty (30) will apply and will expire SIX (6) MONTHS fit cause the application to become ABANDC	e timely filed days will be considered timely. om the mailing date of this communication. NED (35 U.S.C. § 133).	
Status				
1)⊠	Responsive to communication(s) filed on 10 M			
	This action is FINAL . 2b)⊠ This action is non-final.			
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.				
Dispositi	on of Claims			
5)□ 6)⊠ 7)⊠	Claim(s) 22-34 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. Claim(s) 22-34 is/are rejected. Claim(s) 22-34 is/are objected to. Claim(s) are subject to restriction and/or election requirement.			
Applicati	on Papers			
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority u	inder 35 U.S.C. § 119			
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
Attachmen		۰	(DTO 442)	
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date <u>20030925</u> .	4) Interview Summ Paper No(s)/Ma 5) Notice of Inform 6) Other:		

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species I, **claims 22-34**, directed to Figures 6 and 7, in the reply filed on May 10, 2004 is acknowledged.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

- 3. The abstract of the disclosure is objected to because the length may exceed the allowable length of 150 words. Based on an estimate of 10 words per line, and given the fact that the abstract is 21 lines long, the examiner believes that the abstract may exceed the 150-word limit. Correction is required. See MPEP § 608.01(b).
- 4. The disclosure is objected to because of the following informalities: in the Preliminary Amendment, on page 3, the phrase now Patent No. 6,672,307 B2, should be inserted after "August 7, 2002,". Appropriate correction is required.

Claim Objections

5. Claims 22-34 are objected to because of the following informalities: the examiner believes that in claim 22, "flexibly" should be deleted and – flexible – inserted therefor. If necessary, appropriate correction is required.

Double Patenting

- 6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
- 7. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
- 8. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).
- 9. Claims 22-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,672,307 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 22-34 of the instant application are a broader recitation of the invention claimed in claims 1-13 of the '307 patent.

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Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 11. Claims 22-23, 26-29, 32 and 34 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nielson (US 3,004,535).
- 12. Regarding claims 22, 29 and 34, Nielson discloses a quick-donning full face oxygen mask A with a flexible periphery conformable to a wearer's face (column 1, lines 44-49), a flexible optical lens [or insert, as referred to by Nielson] of optical quality disposed in the flexible mask assembly, which allows a wide field of view to the wearer (column 2, lines 55-69), and a face seal (column 3, lines 27-31), as shown in Figure 1.
- 13. Regarding the material from which the optical lens and/or the flexible mask assembly are formed, as found in claims 23, 26-29 and 32, the optical lens [or insert] "is a flexible elastomeric assembly which has a flexibility similar to the mask A, and it may be either a plasticized synthetic resin elastomer, for example, such an elastomer having a vinyl resin base, or preferably, it is composed of a natural rubber having a softness and flexibility comparable to that of the mask A for facilitating folding, unpacking and quick adjustability with respect to wearing with the mask" (column 3, lines 37-44). As shown in Figure 1, the material is transparent or clear such that it facilitates the ability of the wearer to see *through* the insert. The mask A is constructed of "a flexible inert material such as rubber so that they can be adjusted to faces of

different widths." According to *The American Heritage*® *Dictionary of the English Language, Third Edition, silicone* is defined as "any of a group of semi-inorganic polymers based on the structural unit R₂SiO, where R is an organic group, characterized by wide-range thermal stability, high lubricity, extreme water repellence, and physiological inertness and used in...synthetic rubber..." and elastomer is defined as "any of various polymers having the elastic properties of natural rubber." Therefore, Nielson discloses a flexible mask formed of the same material as the instant invention, including such a material that is "optically transparent."

Claim Rejections - 35 USC § 103

- 14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 15. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-25 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable 17. over Nielson (US 3,004,535) in view of Boeckeler (US 4,800,123) or Lim et al. (US 5,880,171). Nielson discloses a quick-donning full face oxygen mask A comprising all the limitations recited in claims 24-25 and 33, with the exception of an optical lens coating with a scratch (or abrasion) resistant additive or coating of clear urethane. However, the use of scratch- and abrasion-resistant coatings was known at the time the invention was made. Specifically, Boeckeler or Lim et al. teaches the use of scratchand abrasion-resistant coatings on optical lens in order to preserve the surface of optically clear lenses by preventing them from being scratched. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the optical lens insert of the mask of Nielson by coating the lenses with a coating of clear urethane because it is well known in the art, as taught by Boeckeler or Lim et al., to coat optical lenses with a coating of clear urethane in order to preserve the surface of optically clear lenses by preventing them from being scratched after the application of this type of abrasion- or scratch-resistant coating.

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- 18. **Claim 30** is rejected under 35 U.S.C. 103(a) as being unpatentable over Nielson (US 3,004,535) in view of Aulgur et al. (US 4,915,106) or Landis (US 5,269,296). Nielson discloses a quick-donning full face oxygen mask **A** comprising all the limitations recited in **claim 30**, with the exception of an inflatable harness formed of silicone tubing. However, the use of an inflatable harness formed of silicone tubing was known at the time the invention was made. Specifically, Aulgur et al. or Landis teaches the use of "a harness strap which can be inflated to a somewhat rigid, self-sustaining orientation to permit one-handed placement of the respirator over the wearer's head" ('106, Abstract) or "an inflatable air strap harness to position and hold the nasal cannulae device relative to the patient's head" ('296, Abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the mask of Nielson by adding an inflatable harness formed of silicone tubing because it is well known in the art, as taught by Aulgur et al. or Landis, to utilize an inflatable harness in order to secure a breathing apparatus snugly, yet comfortably, to the wearer's head.
- 19. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nielson (US 3,004,535) in view of Bauer et al. (US 5,040,530). Nielson discloses a quick-donning full face oxygen mask A comprising all the limitations recited in claim 31, with the exception of the flexible mask assembly and the optical lens being formed as a single piece of transparent silicone. However, the use of a single-piece-construction mask was known at the time the invention was made. Specifically, Bauer et al. teaches the use of mask formed of a single piece of material for providing a "breathing mask which is simple in design, rugged in construction and economical to manufacture"

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(column 2, lines 61-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the construction of the mask of Nielson by altering the entire mask, including the optical lens, to be constructed from the same piece of material because it is well known in the art, as taught by Bauer et al., to construct a breathing mask from one piece of the same material in order to easily manufacture the mask at a low cost.

Conclusion

- 20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dym (US 2,108,256), Meunier (US 4,926,853), Hannah et al. (US 5,941,245), McDonald et al. (US 5,954,052), Bertheau et al. (US 6,039,045), McDonald et al. (US 6,070,580), Resnick (US 6,302,103 B1), McDonald et al. (US 6,443,155 B1) and Little et al. (US H883) all disclose oxygen masks.
- 21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **703-306-4055**. The examiner can normally be reached on Monday through Friday from 8 am until 4:30 pm.
- 22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
- 23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR/WK

Herier Bonnett

Supervisory Print Examiner